

supplementing and formatting a portion of said compliance data to create modified compliance data; . . . [and] classifying said modified compliance data within said database based on a classification scheme relating to [said] compliance data.” (Emphasis added.) Similarly, claim 13 describes a computer system for managing compliance data comprising “a database for organizing said modified compliance data based on a classification scheme relating to [said] compliance data.” (Emphasis added.) As such, the modified compliance data is classified or organized based on a classification scheme related to the compliance data.

For example, in an embodiment of the invention, the compliance data is supplemented, i.e., the content of the compliance data is modified, and the supplemented compliance data is formatted resulting in modified compliance data. The modified compliance data then may be classified or organized into one of thirteen categories. These thirteen categories may be: (1) type of industry, e.g., medical, nuclear, and aerospace, in which the compliance data is applicable; (2) type of compliance subject, e.g., medical device, nuclear facility, or passenger airplane, that the compliance data addresses; (3) continent(s) where the compliance subject is developed and manufactured, e.g., North America, Asia, Europe, or combinations thereof; (4) continent(s) where the compliance subject is used; (5) source of the compliance data, e.g., international standard, national law, guidance document, tool, book, or the like; (6) continent(s) of environmental impact of the compliance subject; (7) countries where the compliance subject is developed and manufactured, e.g., United States, Japan, or both; (8) countries where compliance subject is used; (9) countries of environmental impact of the compliance subject; (10) compliance requirements for subject prior to and during the use of the subject, e.g., submissions to have subject approved prior to use or inspections or subject during operation; (11) common elements of compliance requirements for subject, e.g., types of testing or reporting; (12) business compliance needs for pre/post use of subject, e.g., the answers to question, such as what needs to be done for subject to become compliant, why it needs to be done, and how it can be done; and (13) perspectives of the end-users for pre/post use of subject, e.g., compliance authorities, manufacturers, consumers. See, e.g., Appl’n, Page 8, Lines 13-29. In sum, the above categories address the anticipated uses of the compliance data and are applicable to all types of compliance data.

In contrast, Hall describes a descriptive data structure 200 (“DDS”) which is associated with a rights management data structure, e.g., a newspaper 102 or a magazine 106.

DDS 200 includes DDS definitions 202. For example, when the rights management data structure is newspaper 102, DDS definitions 202 define a generic format that a newspaper style publication could use. Specifically, A first DDS definition 202a does not specify a particular headline of newspaper 102, e.g., Yankees Win the Pennant, but instead defines a location of the headline within newspaper 102. Because DDS 200 is generic to a class or a family of style content publications, it can be reused. See, e.g., Hall, Column 10, Lines 58-68; and Column 11, Lines 1-3. In another example, when rights management data structure is magazine 106, because magazines typically do not include headlines or breaking news, DDS 200 may not define such formatting. Instead, DDS 200 for magazine 106 may define issue date, a magazine title, the name of the photographer, and associated artwork designation.

The Office Action alleges that Hall's rights management data structure corresponds to Applicant's claimed compliance data. See, e.g., Office Action, Page 2, Line 18. Applicant respectfully disagrees. Specifically, Applicant's specification states that "compliance data informs, instructs, or guides users **to act in accordance with a compliance authority's rules or expectations**, e.g., a product manufacturer, such as a drug or medical device manufacturer, establishes procedures for shippers or couriers to eliminate or reduce mix-ups, damage, deterioration, contamination, or other adverse effects to a product during handling." Appl'n, Page 1, Lines 23-27 (emphasis added.). In contrast, rights management data is associated with the management of who has been authorized to access specific files and/or content for issues associated with security. Consequently, Hall's rights management data is not related to Applicant's claimed compliance data.

The Office Action also alleges that Hall's rights management data is "supplemented," as described in Applicant's claims 1 and 13. Applicant respectfully disagrees. Specifically, in Applicant's claimed invention, the compliance data is supplemented, i.e., the content of the compliance data is modified, and the supplemented compliance data then is formatted. (Emphasis added.) For example, a portion of the gathered compliance data may be removed, and the remaining portion of the compliance data may be formatted to generate the modified compliance data. In contrast, although the data in Hall may formatted, the content, i.e., the text, of the data is not modified. Consequently, Hall's data is not supplemented as set forth in claims 1 and 13.

Assuming arguendo that Hall's "rights management data" structure may properly correspond to Applicant's claimed "compliance data," and that Hall's data is "supplemented," Applicant understands that the Office Action alleges that Hall's DDS corresponds to Applicant's claimed modified compliance data. Citing to Column 7, Lines 4-40 of Hall, the Office Action also alleges that Hall describes classifying the modified compliance data (the DDS) within a database based on a classification scheme relating to the compliance data (the rights management data), as set forth in claims 1 and 13. See, e.g., Office Action, Page 2, Lines 19-20. Applicant respectfully disagrees.

Specifically, Hall states that "two or more DDS's may be associated with a container and/or container contents, as well as, for example, one or more user and/or user classes. A choice among two or more possible DDS's for a given container and/or class of containers and/or container contents may therefore be based upon [the] one or more classes and/or [the] one or more classes may be based on parameter data." See, e.g., Hall, Column 6, Lines 39-41; and Column 7, Lines 4-11.

Applicant's claims 1 and 13 require that the modified compliance data be organized based on a classification scheme relating to the compliance data. (Emphasis added.) Nevertheless, because the modified compliance data (DDS) classes are based on "parameter data," Applicant maintains that the modified compliance data (DDS) classes are not based on the "rights management data" which the Office Action alleges corresponds to Applicant's "claimed compliance data." Applicant also maintains that the Office Action fails to satisfy its burden of establishing that Hall's "parameter data" may correspond to Hall's "rights management data." Therefore Applicant respectfully requests that the Examiner withdraw the anticipation rejection of claims 1 and 13. Claims 2-12 and 14-19 depend from claims 1 and 13, respectfully. Therefore, Applicant respectfully requests that the Examiner also withdraw the anticipation rejection of claims 2-12 and 14-19.

CONCLUSION

Applicant respectfully submits that this application is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that an interview with Applicant's representatives, either in person or by telephone, would expedite prosecution of this application, we would welcome such an opportunity. Applicant believes that no fees are due as a

result of this response. Nevertheless, in the event of any variance between the fees determined by Applicant and those determined by the U.S. Patent and Trademark Office, please charge any such variance to the undersigned's Deposit Account No. 02-0375.

Respectfully submitted,

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